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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,180	01/05/2005	Hisao Nishikawa	029650-162	7679

7590 05/19/2006  
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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/520,180

Applicant(s)

NISHIKAWA ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/27/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama (JO 09-276403) in view of Trudell et al (US 5593393) in further view of Melker (US 5242410). Maruyama discloses a needle 1 comprising a puncture point 4; a proximal end 12 having greater outside and inside diameters than the puncture section; and a tapered section T providing puncture resistance smaller than the puncture section, wherein the tapered section has tapered inner and outer profiles. See Figs. 4, 5, 6.

3. Claim 1 differs from Maruyama in calling for the proximal section to have an outside diameter ranging from 0.35 to 1 mm, the puncture section to have a diameter of 0.1 to 0.5 mm. Trudell teaches a puncturing device having a proximal section with a 0.636 mm outer diameter (23 gauge) and a puncture section with a 0.406-0.57 mm (26 or 27 gauge), the smaller diameter allows for the needle to make as small a puncture as possible for the procedure (Col. 4, lines 5-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of

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invention to modify the device of Maruyama to have the dimensions as taught by Trudell to for the needle to make as small a puncture as possible for the procedure.

4. Claim 1 further differs from the teachings of Maruyama in view of Trudell in calling for the tapered section to have an outer profile with an angle ranging from 0.5 to 2 degrees. Melker teaches a needle 1 with a taper from the distal end 5 to the transition point 6 having an angle in the range from about 1.26 degrees to about 5.18 degrees. This taper provides a suitable degree of gentle entry into a vessel, while permitting the introducer to be of reasonable length (Col. 4, lines 27-35). See Fig. 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maruyama in view of Trudell to have a taper of about 1.26 degrees as taught by Melker to provide a suitable degree of gentle entry into a vessel while permitting the introducer to be of reasonable length.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 4781691) in view of Trudell et al (US 5593393) in further view of Melker (US 5242410).

6. Gross discloses a stepped needle comprising a liquid container 40 capable of holding liquid therein; an injection needle 10 having a puncture section 20 capable of piercing a living body; a proximal end section 14 having outside and inside diameters greater than said puncture section; a tapered section 18 providing puncture resistance smaller than the puncture section; a base body 12 supporting the needle, wherein the tapered section and the puncture section protrude from the base body. See Figs. 2 and 6. Gross further discloses that the injection needle

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has a liquid introducing needle section that can communicate with the liquid container. See Fig.

2.

7. Claim 4 differs from Gross in calling for the proximal section to have an outside diameter ranging from 0.35 to 1 mm, the puncture section to have a diameter of 0.1 to 0.5 mm. Trudell teaches a puncturing device having a proximal section with a 0.636 mm outer diameter (23 gauge) and a puncture section with a 0.406-0.57 mm (26 or 27 gauge), the smaller diameter allows for the needle to make as small a puncture as possible for the procedure (Col. 4, lines 5-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross to have the dimensions as taught by Trudell to for the needle to make as small a puncture as possible for the procedure.

8. Claim 4 further differs from the teachings of Gross in view of Trudell in calling for the tapered section to have an outer profile with an angle ranging from 0.5 to 2 degrees. Melker teaches a needle 1 with a taper from the distal end 5 to the transition point 6 having an angle in the range from about 1.26 degrees to about 5.18 degrees. This taper provides a suitable degree of gentle entry into a vessel, while permitting the introducer to be of reasonable length (Col. 4, lines 27-35). See Fig. 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross in view of Trudell to have a taper of about 1.26 degrees as taught by Melker to provide a suitable degree of gentle entry into a vessel while permitting the introducer to be of reasonable length.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1 and 4 have been considered but are moot in view of the new ground(s) of rejection.

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Melker discloses motivation to combine the taper of that invention with applicant's needle as discussed above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LAB

  
**NICHOLAS D. LUCCHESI**  
**SUPERVISORY PATENT EXAMINER**  
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Laura A Bouchelle  
Examiner  
Art Unit 3763